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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,092

05/25/2006

Steven F. Dowdy

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BUCHANAN, INGERSOLL & ROONEY LLP

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ALEXANDRIA, VA 22313-1404

EXAMINER

DESAI, ANAND U

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

03/19/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/561,092	Applicant(s) DOWDY ET AL.	
	Examiner ANAND U. DESAI	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18, 31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to Amendment filed on November 26, 2007. Claim 32 has been cancelled. Claims 1-16, 18, 31, and 33-36 are currently pending and are under examination.
2. Upon further consideration the finality of the rejection of the office action mailed September 10, 2007 is withdrawn. The indicated allowability of claims is withdrawn in view of the reference(s) to Navarro-Quiroga et al. Rejections based on the cited reference(s) follow.

Withdrawal of Rejections

3. The rejection of claims 1-4, 6, 11-16, 18, and 33 under 35 U.S.C. 112, first paragraph, written description is withdrawn based on the amendments to the claims.
4. The rejection of claims 1-4, 6, 11-16, 18, and 33 under 35 U.S.C. 112, first paragraph, scope of enablement is withdrawn based on the amendment to the claims.
5. The rejection of claims 31, 34, 35, and 36 under 35 U.S.C. 102(a) as being anticipated by Navarro-Quiroga et al. (Molecular Brain Research 105: 86-97 (2002)) is withdrawn based on the amendment to recite particular protein translocation domains.

Maintenance of Rejections

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 13, 14, 15, 16, and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Navarro-Quiroga et al. (Molecular Brain Research 105: 86-97 (2002); Previously cited).

Navarro-Quiroga et al. disclose the synthesis of a fusogenic peptide comprising SEQ ID NO: 3 (GLFEAIAEFIEGGWEGLIEG) conjugated to a heterologous polypeptide and a protein transduction domain (see page 87, Section 2.1, Synthesis of the fusogenic-NT-vector). The neurotensin is the heterologous polypeptide and the poly-L-lysine is the protein transduction domain. The polylysine sequence is known in the art to be a protein transduction domain as evidenced by Park et al. (previously cited in Advisory action). The fusion polypeptide is a population of peptides in a test tube. Some portion of the population of peptides are reasonably interpreted to be the first fusion polypeptide comprising a protein transduction domain and a heterologous polypeptide, and some other portion of the population is reasonably interpreted to be the second fusion polypeptide comprising a protein transduction domain and a fusogenic domain (SEQ ID NO: 3).

Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2-9, 31, and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navarro-Quiroga et al. (Molecular Brain Research 105: 86-97 (2002); Previously cited) in view of Yang et al. (FEBS Letters 532: 36-44 (2002)).

Navarro-Quiroga et al. is discussed above in the 35 U.S.C. 102(a) rejection. Navarro-Quiroga et al. do not disclose the use of a protein transduction domain selected from the group consisting of a peptide comprising a herpes viral VP22 protein, a polypeptide comprising a human immunodeficiency virus (HIV) TAT protein, a polypeptide comprising a homeodomain

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of an Antennapedia protein (Antp HD), and a functional fragment thereof comprising amino acids 47-57 of a TAT protein. Yang et al. state and use the 11 amino acid residues (47-57) from HIV-1 TAT protein for protein transduction activity of heterologous peptides, including diagnostic fluorescent fusion proteins and therapeutic agent thymidine kinase (see page 37, section 2.2. Construction of vectors, see particularly for TAT-TK, and TAT-GFP).

The rationale to support a conclusion that the claim would have been obvious is that the substitution of one known element for another yields predictable results to one of ordinary skill in the art.

It would have been *prima facie* obvious to the person having ordinary skill in the art to exchange the polylysine protein transduction domain with the art recognized TAT polypeptide (47-57) protein transduction domain, because the art has recognized the use of TAT protein transduction domains with fusion peptides for protein transport.

12. Claim 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Navarro-Quiroga et al. (Molecular Brain Research 105: 86-97 (2002); Previously cited), Yang et al. (FEBS Letters 532: 36-44 (2002)) and Takenobu et al. (Molecular Cancer Therapeutics 1: 1043-1049 (2002)).

Navarro-Quiroga et al. and Yang et al. are discussed above. Neither reference discloses the use of tumor suppressor protein p53 as the heterologous polypeptide.

Takenobu et al. disclose the use of p53 with a protein transduction domain for the treatment of oral cancers (see page 1043, Material and Methods, Plasmid Construction and

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Purification of 11R-p53 Fusion Protein). Takenobu et al. also discuss the use of a mutated p53 for protein transduction (see page 1048, left hand column of text, line 8).

It would have been *prima facie* obvious to the person having ordinary skill in the art to conjugate the p53 protein disclosed by Takenobu et al. with the TAT protein transduction domain disclosed by Yang et al., because of the known desire to treat tumors with peptide pharmaceuticals. A person having ordinary skill in the art would have expected to succeed because Takenobu et al. do disclose the use of p53 fusion polypeptides with protein transduction domains.

Conclusion

13. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947.

The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

March 10, 2008

/Anand U Desai, Ph.D./
Patent Examiner, Art Unit 1656